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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,240	06/30/2000	Matthew Joseph Doyle	8147	8182

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THE PROCTER & GAMBLE COMPANY
PATENT DIVISION
HEALTH CARE RESEARCH CENTER
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EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/27/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/607,240

Applicant(s)

Doyle et al.

Examiner

DeCloux, Amy

Art Unit

1644

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 26, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group VII (Claims 7-9) and triclosan as the species of antimicrobial agent and cimetidine as the single species of H2 antagonist, in Paper No. 4, filed 10-26-01 is acknowledged. The traversal is on the ground(s) that the present composition claim and method claim are so closely related that they should be prosecuted in the same application. Upon further consideration, the claims will be examined for the Markush groups of microbial agents (claims 1 and 8) without requiring an election of species. Claims 3 and 8 and any dependent claims thereof, will only be examined for the subgenus of H-2 antagonists. In the instant case it would constitute a serious undue burden on the Examiner to search other recited species of claims 3 and 8 essentially for the reasons of record and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others. The restriction is still deemed proper and is therefore made FINAL.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A) Claims 1-8 are indefinite in the recitation of "whole body health" because it is not clear exactly what said phrase encompasses.

B) Claims 1-8 are indefinite in the recitation of "analogs" because it is not clear exactly what said term encompasses.

C) Claims 1-8 are indefinite in the recitation of "essential" because it is not clear exactly what said term encompasses, ie essential for what purpose or function?

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al (U.S. No. 5,364,616).

'616 teaches a method for treatment and prevention of the oral cavity diseases


of gingivitis or periodontitis comprising the topical administration of the oral cavity of a composition comprising an antimicrobial anti-plaque agent (including numerous agents instantly recited in claims 1-2 and 8), and a histamine-2 receptor antagonist compound (including many agents instantly recited in claim 4) and a pharmaceutically acceptable oral carrier (see entire patent especially the abstract and claims 9-10, 16, 19 and 23, and column 21, lines 5-18, column 18, line 48 and column 19, line 7). '616 further teaches that said oral carrier contains components that are suitable for administration to the oral cavity of a human or lower animal (see entire patent especially column 25, lines 36-40). It is noted that the whole body health benefits are inherent in the referenced methods. Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent. See MPEP 2112-2112.02. Also, see Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Preamble language in claims of patents directed to administration of anticancer drugs are expressions of purposes and intended results, and as such are nonlimiting, since language does not result in manipulative difference in steps of claims. The instant case does not present a situation in which the new use of a process should be considered limiting because it distinguishes process over prior art (Bristol Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001), previously 00-1304 (CAFC 4/20/01).

Therefore, the referenced teachings anticipate the claimed invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640
December 21, 2001


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644